Doc code: IDS

PTO/SB/08a (01-09)

Approved for use through 02/28/2009. OMB 0651-0031

Doc description: Information Disclosure Statement (IDS) Filed

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number 10569316 Filing Date 2006-02-22 First Named Inventor Jean-Sébastien Garrigue Art Unit 1618 Examiner Name Not Yet Assigned Attorney Docket Number PLASSR 3.3-001

					U.S.I	PATENTS			Remove		
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue D	)ate	Name of Pate of cited Docu	entee or Applicant ment	Releva		Lines where ges or Relev	
	1	6509370		2003-01	l-21	Joshi-Hangal e	et al.				
	2	6458373		2002-10	)-01	Lambert et al.					
If you wisl	n to ac	⊔ dd additional U.S. Patei	⊥ nt citatio	n inform	ation pl	ease click the	Add button.		Add		
			U.S.P	ATENT	APPLI	CATION PUBI	LICATIONS		Remove		
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date		of cited Document Releva				Lines where ges or Relev	
	1	20020156124		2002-10	)-24	Gao et al.					
If you wish to add additional U.S. Published Application citation information please click the Add button. Add											
				FOREIG	3N PAT	ENT DOCUM	ENTS		Remove		
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>		Kind Code <sup>4</sup>	Publication Date	Name of Patented Applicant of cited Document	e or V F	vhere Rel	or Relevant	T5
	1	1340497	EP			2003-09-03	Novagali Sas et al.				
	2	0078247	wo			2000-12-28	Baker Norton Phari	ma			

Application Number		10569316
Filing Date		2006-02-22
First Named Inventor Jean-		Sébastien Garrigue
Art Unit		1618
Examiner Name Not Y		et Assigned
Attorney Docket Numb	er	PLASSR 3.3-001

	3	0243765	WO		2002-06-06	Transform Pharmaceuticals Inc et al.		
	4	9511039	WO		1995-04-27	Hexal Pharma Gmbh et al.	English translation of abstract only.	×
	5	9945918	wo		1999-09-16	Napro Biotherapeutics Inc		
If you wis	h to ac	dd additional Foreign Pa	atent Document	citation	information pl	ease click the Add buttor	1 Add	•
			NON-PATEN	NT LITE	RATURE DO	CUMENTS	Remove	
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.						
	1	E. K. Rowinsky, The development and clinical utility of the taxane class of antimicrotubule chemotherapy agents. Annu Rev Med. 48: 353-74 (1997).						
	2	R. T. Liggins, W. L. Hunter, H. M. Burt, Solid-state characterization of paclitaxel. J Pharm Sci. 86: 1458-63 (1997).						
	3	R. E. Gregory, A. F. De Lisa, Paclitaxel: a new antineoplastic agent for refractory ovarian cancer. Clin Pharm. 12: 401-15 (1993).						
	4	A. Sparreboom, O. van Tellingen, W. J. Nooijen, J. H. Beijnen, Nonlinear pharmacokinetics of paclitaxel in mice results from the pharmaceutical vehicle Cremophor EL. Cancer Res. 56: 2112-5 (1996);						
	5	O. van Tellingen, M. T. Huizing, V. R. Panday, J. H. Schellens, W. J. Nooijen, J. H. Beijnen, Cremophor EL causes (pseudo-) non-linear pharmacokinetics of paclitaxel in patients. Br J. Cancer 81: 330-5 (1999).						
	6	R. Cavalli, O. Caputo, M. R. Gasco, Preparation and characterization of solid lipid nanospheres containing paclitaxel. Eur J Pharm Sci. 10: 305-9 (2000);						

Application Number		10569316
Filing Date		2006-02-22
First Named Inventor Jean-		Sébastien Garrigue
Art Unit		1618
Examiner Name Not Y		et Assigned
Attorney Docket Number		PLASSR 3.3-001

7	S. S. Feng, G. F. Huang, L. Mu, Nanospheres of biodegradable polymers: a system for clinical administration of an anticancer drug paclitaxel (Taxol). [In Process Citation]. Ann Acad Med Singapore. 29: 633-9 (2000)), liposomes	
8	P. Crosasso, M. Ceruti, P. Brusa, S. Arpicco, F. Dosio, L. Cattel, Preparation, characterization and properties of sterically stabilized paclitaxel-containing liposomes. J. Controlled Release. 63: 19-30 (2000);	
9	A. Sharma, R. M. Straubinger, Novel taxol formulations: preparation and characterization of taxol-containing liposomes. Pharm Res. 11: 889-96 (1994)), water-soluble prodrugs	
10	J. M. Terwogt, B. Nuijen, W. W. T. B. Huinink, J. H. Beijnen, Alternative formulations of paclitaxel. Cancer Treat Rev. 23: 87-95 (1997); A. Pendri, C. D. Conover, R. B. Greenwald.	
11	Pendr, Antitumor activity of paclitaxel-2'-glycinate conjugated to poly(ethylene glycol): a water-soluble prodrug. Anticancer Drug Des. 13: 387-95 (1998)), emulsions	
12	P. P. Constantinides, K. J. Lambert, A. K. Tustian, B. Schneider, S. Lalji, W. Ma, B. Wentzel, D. Kessler, D. Worah, and S. C. Quay, Formulation development and antitumor activity of a filter-sterilizable emulsion of paclitaxel. Pharm Res. 17: 175-82 (2000);	
13	B. B. Lundberg, A submicron lipid emulsion coated with amphipathic polyethylene glycol for parenteral administration of paclitaxel (Taxol.RTM.). J. Pharm Pharmacol. 49: 16-21 (1997);	
14	P. Kan, Z. B. Chen, C. J. Lee, I. M. Chu, Development of nonionic surfactant/phospholipid o/w emulsion as a paclitaxel delivery system. J Controlled Release. 58: 271-8 (1999),	
15	P. Simamora, R. M. Dannenfelser, S. E. Tabibi, S. H. Yalkowsky, Emulsion formulations for intravenous administration of paclitaxel. PDA J Pharm Sci Technol. 52: 170-2 (1998)) and microspheres	
16	R. T. Liggins, S. D'Amours, J. S. Demetrick, L. S. Machan, H. M. Burt, Paclitaxel loaded poly(L-lactic acid) microspheres for the prevention of intraperitoneal carcinomatosis after a surgical repair and tumor cell spill [In Process Citation]. Biomaterials. 21: 1959-69 (2000);	
17	Y. M. Wang, H. Sato, I. Adachi, I. Horikoshi, Preparation and characterization of poly(lactic-co-glycolic acid) microspheres for targeted delivery of a novel anticancer agent, taxol. Chem Pharm Bull (Tokyo). 44: 1935-40 (1996).	

Application Number		10569316
Filing Date		2006-02-22
First Named Inventor Jean-		Sébastien Garrigue
Art Unit		1618
Examiner Name Not Y		et Assigned
Attorney Docket Number		PLASSR 3.3-001

18	J. M. M. Terwogt, M. M. Malingre, J. H. Beijnen, W. W. B. Huinink, H. Rosing, F. J. Koopman, O. van Tellingen, M. Swart, and J. H. M. Schellens, Coadministration of oral cyclosporin A enables oral therapy with paclitaxel. Clin Cancer Res. 5: 3379-84 (1999).	
19	R. T. Dorr. Pharmacology and toxicology of Cremophor EL diluent. Ann Pharmacother. 28: S11-4 (1994); A. J. ten Tije, J. Verweij, W. J. Loos, and A. Sparreboom, Pharmacological effects of formulation vehicles: implications for cancer chemotherapy. Clin Pharmacokinet 42: 665-85 (2003).	
20	C. D. Britten, S. D. Baker, L. J. Denis, T. Johnson, R. Drengler, L. L. Siu, K. Duchin, J. Kuhn, and E. K. Rowinsky, Oral paclitaxel and concurrent cyclosporin A: targeting clinically relevant systemic exposure to paclitaxel. Clin Cancer Res. 6: 3459-68 (2000)).	
21	H. A. Bardelmeijer, M. Ouwehand, M. M. Malingre, J. H. Schellens, J. H. Beijnen, and O. van Tellingen, Entrapment by Cremophor EL decreases the absorption of paclitaxel from the gut. Cancer Chemother Pharmacol 49: 119-125 (2002);	
22	M. M. Malingre, J. H. Schellens, O. Van Tellingen, M. Ouwehand, H. A. Bardelmeijer, H. Rosing, F. J. Koopman, M. E. Schot, W. W. Ten Bokkel Huinink, and J. H. Beijnen, The co-solvent Cremophor EL limits absorption of orally administered paclitaxel in cancer patients. Br J. Cancer 85: 1472-1477 (2001).	
23	J. van Asperen, O. van Tellingen, A. Sparreboom, A. H. Schinkel, P. Borst, W. J. Nooijen, and J. H. Beijnen, Enhanced oral bioavailability of paclitaxel in mice treated with the P-glycoprotein blocker SDZ PSC 833. Br J. Cancer. 76: 1181-3 (1997);	
24	M. M. Malingre, J. M. Terwogt, J. H. Beijnen, H. Rosing, F. J. Koopman, O. van Tellingen, K. Duchin, W. W. Huinink, M. Swart, J. Lieverst, and J. H. Schellens, Phase I and pharmacokinetic study of oral paclitaxel. J Clin Oncol 18: 2468-2475. (2000).	
25	C. M. Kruijtzer, J. H. Schellens, J. Mezger, M. E. Scheulen, U. Keilholz, J. H. Beijnen, H. Rosing, R. A. Mathot, S. Marcus, H. van Tinteren, and P. Baas, Phase II and pharmacologic study of weekly oral paclitaxel plus cyclosporine in patients with advanced non-small-cell lung cancer. J Clin Oncol 20: 4508-16 (2002).	
26	T. Gershanik, S. Benita, Self-dispersing lipid formulations for improving oral absorption of lipophilic drugs. Eur J Pharm Biopharm. 50: 179-88 (2000).	
27	N.H. Shah, M. T. Carvajal, C. I. Patel, M. H. Infeld, A. W. Malick, Self-emulsifying drug delivery systems (SEDDS) with polyglycolyzed glycerides for improving in vitro dissolution and oral absorption of lipophilic drugs. Int J Pharm. 106: 15-23 (1994).	
28	D. J. Hauss, S. E. Fogal, J. V. Ficorilli, C. A. Price, T. Roy, A. A. Jayaraj, and J. J. Kierns, Lipid-based delivery systems for improving the bioavailability and lymphatic transport of a poorly water-soluble LTB4 inhibitor. J Pharm Sci. 87: 164-9 (1998).	

Application Number		10569316
Filing Date		2006-02-22
First Named Inventor Jean-		Sébastien Garrigue
Art Unit		1618
Examiner Name Not Y		et Assigned
Attorney Docket Number		PLASSR 3.3-001

	29	P. P. Constantinides, Lipid microemulsions for improving drug dissolution and oral absorption: physical and biopharmaceutical aspects. Pharm Res. 12: 1561-72 (1995).						
	30	A. J. ten Tije, J. Verweij, W. J. Loos, and A. Sparreboom, Pharmacological effects of formulation vehicles: implications for cancer chemotherapy. Clin Pharmacokinet 42: 665-85 (2003).						
	31	C. M. Kruijtzer, H. Boot, J. H. Beijnen, H. L. Lochs, F. X. Pamis, A. S. Planting, J. M. Pelgrims, R. Williams, R. A. Mathot, H. Rosing, M. E. Schot, H. Van Tinteren, and J. H. Schellens, Weekly oral paclitaxel as first-line treatment in patients with advanced gastric cancer. Ann Oncol 14: 197-204 (2003).	31 Ma					
	32	M. M. Malingre, J. H. Beijnen, H. Rosing, F. J. Koopman, O. van Tellingen, K. Duchin, W. W. Ten Bokkel Huinink, M. Swart, J. Lieverst, and J. H. Schellens, A phase I and pharmacokinetic study of bi-daily dosing of oral paclitaxel in combination with cyclosporin A. Cancer Chemother Pharmacol 47: 347-54 (2001).	32 Sw					
	33	M. Andreeva, P. D. ledmann, L. Binder, V. W. Armstrong, H. Meden, M. Binder, M. Oellerich, A simple and reliable reversed-phase high-performance liquid chromatographic procedure for determination of paclitaxel (taxol) in human serum. Ther Drug Monit. 19: 327-32 (1997);						
	34	A. Sharma, W. D. Conway, R. M. Straubinger, Reversed-phase high-performance liquid chromatographic determination of taxol in mouse plasma. J Chromatogr B Biomed Appl. 655: 315-9 (1994).						
	Sparreboom, A., van Tellingen, O., Nooijen, W. J., and Beijnen, J. H., Determination of paclitaxel and metabolites in mouse plasma, tissues, urine and faeces by semi-automated reversed-phase high-performance liquid (chromatography. J Chromatogr B Biomed Appl, 664: 383-391 (1995).							
	S. Tenjarla. Microemulsions: an overview and pharmaceutical applications. Crit Rev Ther Drug Carrier Syst. 16: 461-521 (1999).							
	37 International Search Report, PCT/IP2004/003077.							
If you wis	If you wish to add additional non-patent literature document citation information please click the Add button Add							
	EXAMINER SIGNATURE							
Examiner	Signa	ure /Jake Vu/ Date Considered 11/20/2009	r Signature					
	*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

( Not for submission under 37 CFR 1.99)

Application Number		10569316
Filing Date		2006-02-22
First Named Inventor Jean-		Sébastien Garrigue
Art Unit		1618
Examiner Name Not Y		et Assigned
Attorney Docket Numb	er	PLASSR 3.3-001

/Jake Vu/

11/20/2009

<sup>&</sup>lt;sup>1</sup> See Kind Codes of USPTO Patent Documents at <u>www.USPTO.GOV</u> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.